VALIDATION RESULTS FOR METHOD NO. Covance Harrogate 2001-030-D1

		MEAN	RELATIVE STD. DEV.(%)	RANGE	SEE (conc)
ANALYTE	3-ABP				
MATRIX	Blood				
DATE	10-Aug-01				
LLOQ	(Acceptance Criteria)	pg/g Hb. Accuracy 100%. RSD 9.6%			
STANDARD ERROR OF ESTIMATE OF QC SAMPLES (concentration units) (SEE = S.D./SQRT (# of determinations))					
	1.5 pg/g Hb	Low QC			0.032
	100 pg/g Hb	Med QC			2.158
	350 pg/g Hb	High QC			6.309
DESCRIPTIVE INFORMATION ON INSTRUMENT RESPONSE					
Function (Linear, Quatradtic, etc.)	Linear				
Slope (mean)	0.0177701				
Intercept (mean)	0.0011253				
Other (mean regression value)	0.999577(1/x weighted)				
RECOVERY (as a %)					
High QC in (matrix)=	350 pg/g Hb	90.00%			
Med QC in (matrix)=	100 pg/g Hb	72.60%			
Low QC in (matrix)=					
Results with different sample amounts (results of QC evaluations) Intra-assay					
LLOQ QC=	0.5 pg/g Hb	0.5	9.60%	0.43-0.57	0.02
Low QC=	1.5 pg/g Hb	1.45	3.40%	1.39-1.50	0.02
Med QC=	100 pg/g Hb	102.33	1.40%	100.23-104.21	0.595
High QC=	350 pg/g Hb	351.47	1.70%	340.59-356.91	2.395
Results with different sample amounts (results of QC evaluations) inter-assay					
LLOQ QC=	n/a	n/a	n/a	n/a	n/a
Low QC=	1.5 pg/g Hb	1.47	5.40%	1.29-1.61	0.032
Med QC=	100 pg/g Hb	99.96	5.30%	86.42-105.78	2.158
High QC=	350 pg/g Hb	341.9	4.50%	309.52-358.87	6.309
STABILITY (assuming any degradation is linear):					
a) Room Temperature in Matrix (+/- %/24 hrs)		13.3% maximun			
b) Freeze/thaw (+/-% /3 cycles)		-3.1% maximum			
c) Injector (+/- %/24 hrs)	300 hrs at nom. -20°C	-2.1% maximum			